REMARKS

Status of Claims

Claims 1-35 and 37-44 are pending in the application and rejected. Claims 1, 3, and 40 have been amended. No new matter has been added. Support for the amendments can be found in the original application as filed on August 4, 1998.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 1-6, 12-19 and 25-35 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US Patent 5,472,441), in view of Edwards (US Patent 5,836,906) in still further view of Swanson (US Patent 6,267,760), and still further view of Lennox et al (US Patent 5,919,191). The Examiner states that Edwards et al., substantially discloses the device of the present application, except it fails to explicitly disclose use of microwave but does disclose the known use of microwave energy to treat the tissue with the use of cooling fluid to prevent undue damage. The Examiner states that Edwards et al, also fails to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. The Examiner states that Edwards et al. discloses high-frequency currents used in electrocautery procedures for cutting human tissue, especially for desired blood-less incisions and areas inaccessible with a scapel. The Examiner states the combination of the prior art, it would have been obvious to one of ordinary skill in the art to modify the Edwards et al. device to incorporate the teaching of Edwards to use microwave (electromagnetic) energy as an alternative means of heating tissue to 20°C - 30°C, which is well known in the art to greatly reduce the blood flow in the tissue. Further, the Examiner states Swanson teaches a device and methods of heating tissue and making an incision in treated tissue after heating in order to reduce blood flow and verify coagulation depth in treated tissue, with the teaching of Lennox et al. to coagulate tissue prior to resection in order to effect essentially bloodless tissue removal, reducing complications, fluid absorption, time in surgery and patient trauma.

The Examiner states that the combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line, therefore it would have

been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., with the teachings of the prior art to achieve the claimed invention.

The Examiner rejected dependent claims 7-11, 20-24, under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US Patent 5,472,441), in view of Edwards (US Patent 5,836,906) in still further view of Swanson (US Patent 6,267,760), and still further view of Lennox et al (US Patent 5,919,191).

The Examiner rejected claims 37-44 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al., in view of Swanson, and further in view of Lennox. The Examiner states Edwards et al. substantially discloses the device of the present application, except, in addition to the above, fails to explicitly disclose bloodless resection of tissue. The Examiner states that with the combination of the prior art it would have been obvious to one of ordinary skill in the art to modify the Edwards et al. device to achieve the claimed invention. The Examiner states that "bloodlessly resecting the tissue from the body" is broadly equivalent to "severing the tissue from the body" without excessive bleeding.

The Examiner rejected dependent claim 38 in view of Swanson and further view of Lennox et al, stating the prior art disclose the claimed invention as the tissue heat-treating device makes an ablation lesion locally and the device must be removed to allow the lesion area be free to be incised.

The Examiner rejected dependent claim 39, in view of Edwards et al, in view of Swanson and further in view of Lennox et al., as the prior art disclose the claimed invention.

The Examiner rejected dependent claims 41, 42, 43, and 44 stating Edwards et al discloses the claimed invention.

The Examiner states that the dependent claims in the present application are substantially disclosed in Edwards et al.

Applicants traverse the rejection and respectfully request reconsideration. Applicants have amended independent claims 1, 3, and 37 to specifically state that providing an array of

needles is providing an array of needles that are arranged in a rectangular pattern on the applicator face in an array of two by two needles. Applicants respectfully suggest that this is not made obvious by the prior art of record.

Edwards et al. '441 disclose that his needles can be arranged in a grid pattern. However, simply because Edwards et al. disclose a "grid pattern" that does not necessarily mean that all possible configurations are obvious. Edwards et al. is not enabled for *any* configuration of a needle array other than a single row of needles because Edwards et al. do not disclose how all grid-like configurations of needle arrays would work. In fact, Edwards et al. do not disclose how even one grid pattern would work. For example, Edwards et al. disclose a device that is designed to penetrate a tumor to destroy or ablate the tumor *in situ*. The tumor is not removed from the patient's body. If any configuration of needles were possible then such a hypothetical configuration might extend beyond the boundary of the tumorous structure and destroy healthy tissue, which Edwards et al. specifically seeks to avoid. Edwards et al. seeks to preserve healthy tissue. Col. 4:67- col. 5:1 *Cf.* col. 2:19-22. The disclosure by Edwards et al. of a "grid" pattern is simply a non-enabled "throw-away" reference to a configuration that may or may not work. There are an infinite number of grid patterns possible, including those having interior needles. However, only certain patterns would be suitable to be centered on a selected incision. In other words, hardly any of the possible infinite number of grid patterns would form a "channel" as explicitly claimed by Applicants in at least claim 1.

Moreover, it is not obvious to try the array of two by two needles claimed by Applicants. The Federal Circuit has long held that "obvious to try" is not the standard by which obviousness is measured. E.g., In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1599 (Fed.Cir.1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed.Cir.1987); In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 379 (Fed.Cir.1986); In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977). Where one of ordinary skill in the art must try numerous possible choices until he arrived at a successful result, where the prior art *gave no indication of which parameters were critical or no direction as to which of the many possible choices is likely to successful*, then the claimed invention is not obvious. *In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)*. Therefore, one or ordinary skill in the art would not be motivated to select the particular grid pattern chosen by Applicants (despite the fact that it is

simple indeed) because one skilled in the art would need to conduct endless experimentation of an infinite number of grid possibilities with no reasonable expectation of success of hitting the precise grid pattern claimed by Applicants. A prior art suggestion for virtually endless experimentation does not make a prima facie case of obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1989).

Applicants have submitted herewith an IDS of twenty three medical journal articles/abstracts that detail the successful use of an array of two by two needles in liver surgery. Applicants have also submitted one article ("Lupo et al.") from the British Journal of Surgery 2007; 94:287-291 that tested a straight line of needles (See FIG. 2) (similar to those disclosed in Edwards et al. '441) in liver surgery and concluded that a higher rate of postoperative complications resulted including loss of blood during surgery. In summary, the planar line of six needles tested by Lupo et al. do not yield positive results for liver surgery. This is evidence enough that needles arranged in a rectangular pattern of two needles by two needles is not made obvious by Edwards et al. '441 or the combination of art cited by the Examiner.

The Examiner has cited the combination of Edwards et al. '441 in view of Edwards et al. '906 and further in view of Swanson '706 and further in view of Lennox et al. '191. In particular, the Examiner states that Swanson '706 discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue citing to col. 8, lines 33-41. Applicants respectfully disagree. A problem with the disclosure of Swanson is that the size of vessels which bleed during liver surgery is approximately 10 mm in diameter. In order to close or coagulate such a vessel, Applicants have discovered that the length of the needle must be equal to at least double the length of the diameter of the vessel. A single straight needle such as that disclosed by Swanson '706 (and Edwards '441 and '906) cannot coagulate a volume of tissue. The needles must be arranged in a rectangular or square pattern as claimed by Applicant in order to coagulate the large blood vessels in the liver during surgery. The passage cited by the Examiner in Swanson states:

> In order to reduce the blood loss associated certain surgical procedures, a surgical method in accordance with another of the present inventions includes the steps of coagulating soft tissue and then forming an incision is the coagulated tissue. If the incision is no deeper than the coagulation, the incision will not result in

significant bleeding. *This process can be repeated until an incision of the desired depth is achieved.*

Swanson, col. 8, lines 33-41. Also see, col. 45, lines 37-40 ("The process of coagulating tissue and then forming an incision in the coagulated tissue can be repeated until the incision reaches the desired depth.")

However, the Swanson method would actually result in substantial bleeding from a vessel in the liver that is of the normal size of approximately 10 mm in diameter. Although the "process of coagulating tissue *and then forming an incision in the coagulated tissue can be repeated until the incision reaches the desired depth*" repeating the process would invariably and necessarily result in substantial bleeding because the necessary depth of the vessel along the planned incision line could not be coagulated at the same time. In other words, repeating the process until the desired coagulation depth is achieved means that the blood vessel would necessarily be punctured or sliced by the subsequent incision and thus result in substantial bleeding.

The Examiner also cites to Lennox '191 in combination with Edwards '441, Edwards '906 and Swanson '760. Specifically the Examiner states that Lennox et al. '191 disclose "to effect substantially bloodless tissue removal which can reduce complications from blood loss, fluid absorption, time in surgery, and patient trauma" and states that this meets the limitation bloodlessly resecting the tissue from the body. However, the combination of art cited by the Examiner does not make the claimed invention obvious. Specifically, none of the art cited by the Examiner makes obvious "providing a device, the device comprising an applicator having at least one face and including an array of four needles arranged in a rectangular pattern of two rows by two columns that define a central channel structured and arranged such that two of said four tissue-piercing needles are positioned on one side of a width of diseased liver tissue and two of said needles are arranged to be positioned on an opposite side of said width of diseased liver tissue, said width of tissue defining a planned incision line corresponding with said channel, said plurality of four tissue-piercing needles structured and arranged to be energizeable together to deliver three-dimensional energy among and with a cross-flow across said plurality of tissue-piercing needles, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of four needles arranged in two rows by two columns such that

two of said four tissue-piercing needles are positioned on one side of a width of diseased liver tissue and two of said needles are positioned on an opposite side of said width of diseased liver tissue such that said positioning defines a planned incision line corresponding with said channel, said array of needles serving to confine and transmit the electromagnetic energy field three-dimensionally; extending the tissue-piercing distal tips of said array of needles from said at least one face of the applicator into said diseased liver tissue at a point on the planned incision line such that said four needles define a volume of liver tissue to be treated; applying said electromagnetic energy three-dimensionally among said array of four needles into the volume of liver tissue at said point on the planned incision line such that localized heating of said volume of liver tissue is achieved and blood vessels within said volume of liver tissue are coagulated; removing the tissue-piercing distal tips of said array of needles from the volume of tissue to be treated; advancing the applicator along the planned incision line in step-wise manner, extending the tissue-piercing distal tips of said array of needles into a subsequent volume of tissue to be treated along said planned incision line, and applying said electromagnetic energy three-dimensionally among said array of four needles into the volume of the tissue to be treated along said planned incision line until said electromagnetic energy has been applied along the length of said incision line and blood vessels in the liver tissue along said planned incision line are coagulated; and severing the diseased liver tissue from the body by incision along said planned incision line without excessive bleeding" as claimed in claim 1. Nor does the combination of art cited by the Examiner make claims 3 or 37 obvious.

With regard to the remaining dependent claims, if an independent claim is allowable so too are the dependent claims. MPEP§2143.03. Applicants respectfully suggest that all claims are allowable over the prior art.

CONCLUSION

All rejections having been addressed Applicant earnestly solicits a Notice of Allowance in this case. If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below.

Applicants hereby petition for a two-month extension of time, the three-month statutory period having expired on October 1, 2009 and the present response being filed on or before December 1, 2009. The Commissioner is hereby authorized to charge or credit any such extension fees or overpayment to Deposit Account No. 50-1901 (Reference #22413-14).

Dated: December 1, 2009

Respectfully submitted,

OPPENHEIMER, WOLFF & DONNELLY LLP
Attorneys for Applicant

By _____

Barbara A. Wrigley
Reg. No. 34,950
45 South 7th Street, Suite 3300
Minneapolis, MN 55402
Telephone No.: (612) 607-7595
Facsimile No.: (612) 607-7100
E-Mail: BWrigley@Oppenheimer.com

Customer No. **34205**